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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,701	01/05/2001	Allan S. Hoffman	UWOTL119001	3998

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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/755,701		HOFFMAN ET AL.	
	Examiner		Art Unit	
	MY-CHAU T. TRAN		1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,8,9,13-17,19,34-36 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,8,9,13-17,19,34-36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/20/2006 has been entered.

Application and Claims Status

2. Applicant's amendment and response filed 06/20/2006 are acknowledged and entered.
3. Claims 2-4, 8, 9, 13-17, 19, 33-36, and 38-44 were pending. Applicants have amended claims 4, 8, 13, 15, 16, 34-36 and cancelled claims 2 and 33. No claims were added. Therefore, claims 3, 4, 8, 9, 13-17, 19, 34-36, and 38-44 are currently pending.
4. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected with traverse the following species for the elected invention (Claims 2-4, 8, 9, 13-17, 19, 33-36, and 38-44) in the reply filed on 5/10/2004 and 8/16/2004):
 - a. For a *single specific* species of hydrophobic component, applicant has elected the terpolymer of dimethylaminoethyl methacrylate (DMAEMA), butyl methacrylate

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(BMA), and styrene benzaldehyde, which is described in Example 2 and illustrated in Figures 4 and 5.

- b. For a *single specific* species of hydrophilic component, applicant has elected polyalkylene oxide (e.g., PEG).
- c. For a *single specific* species of pH-sensitive linkage, applicant has elected acetal.

5. Claims 3, 4, 8, 9, 13-17, 19, 34-36, and 38-44 are under consideration in this Office Action.

Status of Claim(s) Rejection(s) and Indication of Allowable Subject Matter

6. All previous rejections are withdrawn in view of applicant's amendments of claim 36 and cancellation of claim 33. In addition, the indicated allowability of Claims 36 and 38-44 are withdrawn, upon further consideration, new grounds of rejection are made in view of Webber et al. (US Patent 5,955,509), Nair et al. (US Patent 5,078,994) and Vinogradov et al. (*Bioconjugate Chem.*, 1998, 9(6), pgs. 805-812).

New Rejection(s)

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 4 and 38-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For claim 4, the terms “*vinyl-type hydrophobic polymer*” and “*non-vinyl-type hydrophobic polymer*” are vague and indefinite. The addition of the word “type” to an otherwise definite expression (e.g. vinyl, propylene, polystyrene) extends the scope of the expression so as to render it indefinite. See *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). See also MPEP § 2173.05(b). Therefore, claim 4 is rejected under 35 U.S.C. 112, second paragraph.

B. For claims 38 and 39, the term “*vinyl-type polymer*” is vague and indefinite. The addition of the word “type” to an otherwise definite expression (e.g. vinyl, propylene, polystyrene) extends the scope of the expression so as to render it indefinite. See *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). See also MPEP § 2173.05(b). Therefore, claims 38, 39, and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

C. For claims 41 and 42, the term “*vinyl-type polymer*” is vague and indefinite. The addition of the word “type” to an otherwise definite expression (e.g. vinyl, propylene, polystyrene) extends the scope of the expression so as to render it indefinite. See *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). See also MPEP § 2173.05(b). Therefore, claims 41, 42, and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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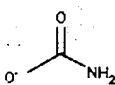
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 3, 4, 8, 14, 15, 19, and 34-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vinogradov et al. (*Bioconjugate Chem.*, 1998, 9(6), pgs. 805-812).

For **claims 4, 35, and 36**, Vinogradov et al. disclose the cationic copolymers for DNA delivery (see e.g. Abstract; pg. 805, right col., lines 31-33; pg. 806, left col., lines 44-65; pg. 807, fig. 1). The cationic copolymers comprises the conjugate of poly(ethylene glycol)(PEG) (refers to instantly claimed hydrophilic component/polyalkylene oxide) and polyamines (refers to instantly claimed hydrophobic component/a non-vinyl-type hydrophobic polymer and instant claims 4 and 35)(see e.g. pg. 805, right col., lines 31-33; pg. 806, left col., lines 44-65; pg. 807, fig. 1; pg. 811, lines left col., lines 57-60). Moreover, the recitation of “*for enhancing transport through a membrane*” in the preamble is not considered a limitation and is of no significance to claim construction since it does not set forth any distinct definition of any of the instantly claimed composition. See MPEP § 2111.02.

For **claims 8 and 36**, in figure 1 of Vinogradov et al. illustrates that the PEG and the

polyamines are linked thru a carbamate linker, i.e.  (HN-COO), (refers to instantly claimed pH-sensitive linkage and instant claim 8).

For **claims 3, 14, 19, and 34**, Vinogradov et al. disclose that the cationic copolymers are complex to the antisense oligonucleotides (PS-ODNs) (refers to instant claims 3, 14, 19, and

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34)(see e.g. pg. 807, right col., line 8 thru pg. 808, right col., line 23; pg. 806, left col., lines 44-65).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of:

For **claims 15 and 36**, the limitations that '*the pH-sensitive linkage is stable at a pH between 6.8 and 8 and hydrolyzed at a pH less than 6.5 to release the hydrophobic component*' and that '*the pH-sensitive linkage is hydrolyzed within about 30 to 60 minutes at a pH between 5.0 and 5.5*'. These limitations are interpreted as the functional limitation for the instantly claimed pH-sensitive linkage. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Vinogradov et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). As a result, the pH-sensitive linkage of Vinogradov et al. would still anticipate the presently claimed pH-sensitive linkage since it meets all the structural limitation of the claimed pH-sensitive linkage that is '*carbamate*' of claim 8.

For **claim 36**, the limitation that '*the hydrophobic component is membrane disruptive and allows enhanced transport through a membrane only when released from the hydrophilic conjugate*', and it is interpreted as the functional limitation for the instantly claimed hydrophobic component. The claimed invention appears to be the same or obvious variations of the reference

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teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Vinogradov et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Consequently, the hydrophobic component of Vinogradov et al. would still anticipate the presently claimed hydrophobic component since it meets all the structural limitation of the claimed hydrophobic component that is '*a non-vinyl-type hydrophobic polymer*' of claim 4 and '*a synthetic polymer*' of claim 35.

Therefore, the composition of Vinogradov et al. anticipates the instantly claimed invention.

11. Claims 3, 4, 8, 9, 13-17, and 34-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nair et al. (US Patent 5,078,994).

For *claims 3, 4, 13, and 34-36*, Nair et al. disclose a pharmaceutical composition comprising a copolymer of vinyl monomers (refers to instantly claimed hydrophobic component/a synthetic vinyl-type hydrophobic polymer and instant claims 4 and 35) and poly(alkylene oxide)(refers to instantly claimed hydrophilic component/polyalkylene oxide), and a therapeutic or diagnostic agent (see e.g. Abstract; col. 2, lines 19-22 and 52-59). The therapeutic agent includes compounds such as biological active substances, pharmaceuticals, enzymes, and recombinant products (refers to instant claims 3, 13, and 34)(see e.g. col. 5, lines

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38-46). Moreover, the recitation of “*for enhancing transport through a membrane*” in the preamble is not considered a limitation and is of no significance to claim construction since it does not set forth any distinct definition of any of the instantly claimed composition. See MPEP § 2111.02.

For **claim 8**, Nair et al. disclose that the attachment between the vinyl monomers and poly(alkylene oxide) is an ester linker (see col. 5, lines 5-11).

For **claims 9, 14, 16, and 17**, Nair et al. disclose that the therapeutic agent is chemically bonded to the copolymers and can be release from the pharmaceutical composition after being administered to a host mammal (see e.g. col. 5, lines 34-37 and 60-66). In addition, the pharmaceutical composition also includes a carrier and is locally delivered to the host mammal (see e.g. col. 5, lines 54-66).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of:

For **claims 15 and 36**, the limitations that ‘*the pH-sensitive linkage is stable at a pH between 6.8 and 8 and hydrolyzed at a pH less than 6.5 to release the hydrophobic component*’ and that ‘*the pH-sensitive linkage is hydrolyzed within about 30 to 60 minutes at a pH between 5.0 and 5.5*’. These limitations are interpreted as the functional limitation for the instantly claimed pH-sensitive linkage. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Nair et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed

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composition is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). As a result, the pH-sensitive linkage of Nair et al. would still anticipate the presently claimed pH-sensitive linkage since it meets all the structural limitation of the claimed pH-sensitive linkage that is an 'ester' of claim 8.

For *claim 36*, the limitation that '*the hydrophobic component is membrane disruptive and allows enhanced transport through a membrane only when released from the hydrophilic conjugate*', and it is interpreted as the functional limitation for the instantly claimed hydrophobic component. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Nair et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Consequently, the hydrophobic component of Nair et al. would still anticipate the presently claimed hydrophobic component since it meets all the structural limitation of the claimed hydrophobic component that is '*a vinyl-type hydrophobic polymer*' of claim 4 and '*a synthetic polymer*' of claim 35.

Therefore, the composition of Nair et al. anticipates the instantly claimed invention.

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12. Claims 38, 40, 41, 43, and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nair et al. (US Patent 5,078,994).

For **claims 38, 41, and 44**, Nair et al. disclose a pharmaceutical composition comprising a copolymer of vinyl monomers (refers to instantly claimed hydrophobic synthetic vinyl-type polymer) and poly(alkylene oxide)(refers to instantly claimed hydrophilic polyalkylene oxide), and a therapeutic or diagnostic agent (see e.g. Abstract; col. 2, lines 19-22 and 52-59). The therapeutic agent includes compounds such as biological active substances, pharmaceuticals, enzymes, and recombinant products (refers to instant claim 44)(see e.g. col. 5, lines 38-46).

For **claims 40 and 43**, Nair et al. disclose that the attachment between the vinyl monomers and poly(alkylene oxide) is an ester linker (see col. 5, lines 5-11).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of:

For **claims 38 and 41**, the limitation that '*the pH-sensitive linkage is stable at a pH between 6.8 and 8 and hydrolyzed at a pH less than 6.5*' is interpreted as the functional limitation for the instantly claimed pH-sensitive linkage. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Nair et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). As a result, the pH-

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sensitive linkage of Nair et al. would still anticipate the presently claimed pH-sensitive linkage since it meets all the structural limitation of the claimed pH-sensitive linkage that is an '*ester*' of claim 8.

For *claims 38 and 41*, the limitation that the hydrophobic synthetic vinyl-type polymer '*is endosomal membrane disruptive when released from the hydrophilic conjugate*' is interpreted as the functional limitation for the instantly claimed hydrophobic synthetic vinyl-type polymer. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Nair et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Consequently, the hydrophobic component of Nair et al. would still anticipate the presently claimed hydrophobic component since it meets all the structural limitation of the claimed hydrophobic synthetic vinyl-type polymer of claims 38 and 41.

Therefore, the composition of Nair et al. anticipates the instantly claimed invention.

Conclusion

13. No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran
Patent Examiner
September 29, 2006

